

Favorable reconsideration is respectfully requested in light of the above amendments and the following comments.

The Examiner objected to the specification as incorporating subject matter by reference.

The Examiner rejected claim 32 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-18, and 32-35 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-10, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Björck et al. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1, 7-8, 10-16, 18, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Cooray et al. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-4, 6-11, 14-17, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Clark et al. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-4, 7, 11, and 15 under 35 U.S.C. § 102(b) as being anticipated by Saugstad et al. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-17, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Ho et al. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-10, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Zikakis. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-11, 13-17, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Antrim. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1, 6-10, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by De Jong et al. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-18 and 32-35 under 35 U.S.C. § 103(a) as being unpatentable over Björck et al., Ho et al, Clark et al., Zikakis, Antrim et al., and De Jong et al. in view of Reddy et al. Applicants respectfully traverse this rejection.

#### **Objection to Specification**

The Examiner objected to the specification as incorporating subject matter by reference to Biozyme product literature. The Examiner indicated that the attempt to incorporate subject matter into the application by reference to Biozyme product literature at page 15, lines 24-26 is improper because the specific activity of the xanthine oxidase (U/ $\mu$ g) used in the examples is critical to relating the  $\mu$ g/ml claimed to the U/ml normally reported for enzymes. The Applicants have added the pertinent information to the specification which would have been found in the Biozyme product literature. No new matter was added by this amendment. Applicants respectfully request withdrawal of this objection.

#### **35 U.S.C. § 112 Rejections**

The Examiner rejected claim 32 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Claim 32 has been cancelled without prejudice or disclaimer of the subject matter contained therein. Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1-18, and 32-35 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner asserts that claim 1, and others recite "active xanthine oxidase" which is vague and indefinite because the degree and magnitude of the "activity" of the xanthine oxidase is unclear. Applicants respectfully assert that the phrase "active xanthine oxidase" is not indefinite because Applicants have defined what the phrase "active xanthine oxidase" means in the specification. Lines 3-7, at page 5 clarify the meaning of the phrase as "XOR and enzyme which has not, for example, been

inactivated or broken down in such a way." Therefore, Applicants respectfully assert that the phrase is definite.

The Examiner also asserts that claims 11-15 are indefinite because they recite a "combination product" which is not accepted terminology. Claims 11-15 have been amended to use the term "kit" in place of "combination product".

The Examiner asserts that the phrase "substantially no active XOR" in claim 11 is indefinite because it is unclear the metes and bounds of the amount of XOR is unclear. Claim 11 has been amended to delete this phrase.

The Examiner asserts that claim 32 is indefinite because it fails to point out what is included or excluded by the claim language. Claim 32 has been cancelled herein.

The Examiner asserts that claim 33-35 are incomplete for omitting essential elements. Claim 33 has been amended to indicate that the amount of active XOR is an amount that is effective to act as a bactericidal agent.

Based on the above comments and amendments to the claims, Applicants respectfully request withdrawal of this rejection.

### 35 U.S.C. § 102 Rejections

The Examiner rejected claims 1-10, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Björck et al. The Examiner asserts that Björck discloses the concentration of xanthine oxidase normally in milk.

Applicants' invention is a "formula feed", which is generally not thought to include within its scope substances such as pasteurized cow's milk, milk powder, lyophilized buttermilk, colostrum, buttermilk, human milk, or general animal feeds. "Formula feed" is generally understood by those of skill in the art to refer to formulations which are specifically designed for feeding to infant humans or animals as a substitute for breast milk, and generally excludes milk products *per se*. In order to make this distinction more clear, claim 1 has been amended to clarify that the formula feed is nutritionally complete. Such an amendment to the claims is supported at least at page 3, lines 25-28.

Björck discloses the concentration of xanthine oxidoreductase in cow's milk. Cow's milk is not a formula feed because it has not been formulated, is not suitable for

not persuasive  
no evidence  
term appears  
to be broader  
milk product based lines 26-27  
26-27

feeding to a human infant, and is not nutritionally complete. Because the composition of Björck is not nutritionally complete, it cannot anticipate the Applicants' invention. Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1, 7-8, 10-16, 18, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Cooray et al. The Examiner states that Cooray discloses milk with added xanthine oxidase, or phosphate synthetic medium with xanthine oxidase. As discussed above, Applicants' invention is a formula feed which is nutritionally complete. The composition of Cooray is not nutritionally complete, and therefore does not anticipate Applicants' invention. Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1-4, 6-11, 14-17, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Clark et al. The compositions of Clark are administered to adult rats and are not nutritionally complete. As discussed above, Applicants' invention is a formula feed which is nutritionally complete. The composition of Clark is not nutritionally complete, and therefore does not anticipate Applicants' invention. Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1-4, 7, 11, and 15 under 35 U.S.C. § 102(b) as being anticipated by Saugstad et al. The compositions of Saugstad are buffered solutions of xanthine oxidoreductase, with no nutritional value. As discussed above, Applicants' invention is a formula feed, which is nutritionally complete. The composition of Saugstad is not nutritionally complete, and therefore does not anticipate Applicants' invention. Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1-17, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Ho et al. The compositions of Ho are very similar to those of Clark, and are administered to adult rats and are not nutritionally complete. As discussed above, Applicants' invention is a formula feed, which is nutritionally complete. The composition of Ho is not nutritionally complete, and therefore does not anticipate Applicants' invention. Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1-10, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Zikakis. Zikakis discloses the concentration of xanthine oxidoreductase in bovine milk. As discussed above, Applicants' invention is a formula feed which is

nutritionally complete. The composition of Zikakis is not nutritionally complete, and therefore does not anticipate Applicants' invention. Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1-11, 13-17, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Antrim. Antrim discloses xanthine oxidoreductase-containing edible fish oil emulsions for use in mayonnaise, salad dressings, and margarine. As discussed above, Applicants' invention is a formula feed which is nutritionally complete. The composition Antrim is not nutritionally complete, and therefore does not anticipate Applicants' invention. Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1, 6-10, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by De Jong et al. De Jong discloses the use of xanthine oxidoreductase to preserve food. As discussed above, Applicants' invention is a formula feed which is nutritionally complete. The composition of De Jong is not nutritionally complete, and does nothing more than act as a preservative, and therefore does not anticipate Applicants' invention. Applicants respectfully request withdrawal of this rejection.

### 35 U.S.C. § 103 Rejection

The Examiner rejected claims 1-18 and 32-35 under 35 U.S.C. § 103(a) as being unpatentable over Björck et al., Ho et al, Clark et al., Zikakis, Antrim et al., and De Jong et al. in view of Reddy et al.

In order to establish *prima facie* obviousness, three basic criteria must be met, namely: (1) there must be some suggestion or motivation to combine the references or modify the reference teaching; (2) there must be a reasonable expectation of success; and (3) the reference or references when combined must teach or suggest each claim limitation. Applicants submit that the Office Action failed to state a *prima facie* case of obviousness, and therefore the burden has not properly shifted to Applicants to present evidence of nonobviousness.

As a preliminary matter, Applicants respectfully assert that a *prima facie* case of obviousness has not been shown because the references, either alone or together, fail to disclose all of the elements of the claimed invention. None of the primary references contain all of the elements of the claimed invention, and the secondary reference, Reddy

et al. does not overcome the deficiencies of the primary references. Reddy et al. does not disclose a nutritionally complete formula feed.

Applicants also assert that there would be no mortification to combine Reddy with the other references, or alternatively, there would not be a reasonable expectation of success. Reddy et al. discloses the use of a peroxidase and a non-enzymatic source of peroxide. One of skill in the art would not contemplate using xanthine oxidoreductase as an alternative source of peroxide because it would be too anaerobic for material amounts of peroxide to be produced. Therefore, the teachings of Reddy would not motivate one of skill in the art to produce the Applicants' invention. Applicants respectfully request withdrawal of this rejection.


### Conclusion

In view of the amendments and comments presented herein, favorable reconsideration in the form of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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In the Specification

Replace the paragraph spanning lines 25-26 at page 15 with the following paragraph:

- 1. Bovine xanthine oxidase (XOR) - Biozyme, Blaenavon, UK.

This source of enzyme had a concentration of 10.7 mg/ml, an activity of 1.0 units/mg, had undetectable levels of lactoperoxidase, and was batch 104AX.-

Marked up version of Claims

1. (Amended) A formula feed for administration to a human or animal, the formulation [including] comprising active xanthine oxidoreductase (XOR), wherein said formula feed is nutritionally complete.

11. (Twice Amended) A [combination product] kit for use in the preparation of a formula feed according to claim 1, [in which the product comprises] comprising a first and second [two separate] portions, the first portion including active XOR and the second portion being sterilized [and comprising substantially no active XOR].

12. (Amended) A [combination product] kit according to claim 11, in which the second portion is in the form of a powder.

13. (Twice Amended) A [combination product] kit according to claim 11, in which the second portion has been heat treated.

14. (Twice Amended) A [combination product] kit according to claim 11, in which the first portion has been pasteurized.

15. (Twice Amended) A [combination product] kit according to claim 11, in which the first portion is in a first container, and the second portion is in a second container.

33. (Amended) A formulation for use as a bactericidal agent in the human or animal digestive system[, the formulation including] comprising an amount of active xanthine oxidoreductase (XOR) effective for use as a bactericidal agent.